commenting would be aggrieved by approval of the proposal.

Comments regarding the application must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than April 21, 1989.

A. Federal Reserve Bank of Minneapolis (James M. Lyon, Vice President) 250 Marquette Avenue, Minneapolis, Minnesota 55480:

1. *Norwest Corporation*, Minneapolis, Minnesota, and two of its subsidiaries, Norwest Financial Services, Inc., Des Moines, Iowa, and Norwest Financial, Inc., Des Moines, Iowa; to acquire substantially all of the assets of Corporate Funding, Inc., Grand Rapids, Michigan, and thereby engage in leasing personal property or acting as agent, broker or advisor in leasing personal property pursuant to § 225.25(b)(5); and making, acquiring or servicing loans or other extensions of credit such as would be made by a commercial finance company pursuant to § 225.25(b)(1) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, March 29, 1989.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 89-7888 Filed 4-3-89; 8:45 am]

BILLING CODE 6210-01-M

GENERAL SERVICES ADMINISTRATION

[G-89-2]

Delegation of Authority to the Secretary of State

Pursuant to the authority vested in me be section 3726 of Title 31, United States Code, I have determined that it is cost-effective or otherwise in the public interest to delegate authority to the Secretary of State to conduct a prepayment audit of transportation bills relating to the movement of unaccompanied air baggage between Washington, DC, and overseas locations, subject to the provisions of the Federal Property Management Regulations, Title 41, Code of Federal Regulations, Supbart 101-41, and amendments thereto. This prepayment audit will be conducted at the Office of Transportation, Department of State, Washington, DC.

The Secretary of State may redelegate this authority to any officer, official, or employee of the Department of State.

The Secretary of State shall notify GSA in writing of these redelegations and their basis. This delegation is effective upon publication in the Federal Register.

Dated: March 23, 1989.

Richard G. Austin,

Acting Administrator of General Services.

[FR Doc. 89-7986 Filed 4-3-89; 8:45 am]

BILLING CODE 6820-24-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 89E-0055]

Determination of Regulatory Review Period for Purposes of Patent Extension; Optiray™

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Optiray™ and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESS: Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Nancy Pirt, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product Optiray™ (ioversol) which is indicated for angiography throughout the cardiovascular system. These include cerebral, coronary, peripheral, visceral and renal arteriography, aortography, and left ventriculography. Optiray™-320 is also indicated for contrast enhanced computed tomographic imaging of the head and body, and intravenous excretory urography. Optiray™-240 is indicated for cerebral angiography and venography. Optiray™-160 is indicated for intra-arterial digital subtraction angiography (IA-DSA). Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Optiray™ (U.S. Patent No. 4,396,598) from Mallinckrodt, Inc., and requested FDA's assistance in determining the patent's eligibility for patent term restoration. FDA, in a letter dated February 21, 1980, advised the Patent and Trademark Office that the human drug product had undergone a regulatory review period and that the active ingredient, ioversol, represented the first permitted commercial marketing or use either alone or in combination with other active ingredients. Shortly thereafter, the Patent and Trademark Office requsted that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Optiray™ is 1,075 days. Of this time, 521 days occurred during the testing phase of the regulatory review period, while 554 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act became effective:* January 22, 1986. FDA has verified the applicant's claim that the investigational new drug (IND) application for Optiray™ became effective on January 22, 1986.

2. *The date the application was initially submitted with respect to the*

human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act: June 26, 1987. The applicant claims that the new drug application for Optiray™ (NDA 19–710) was initially submitted on June 25, 1987. However, FDA records indicate that the application was not received until June 26, 1987.

3. *The date the application was approved:* December 30, 1988. FDA has verified the applicant's claim that NDA 19–710 was approved on December 30, 1988.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 813 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before June 5, 1989, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before October 2, 1989, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, Part 1, 98th Cong., 2d Sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 24, 1989.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 89–7893 Filed 4–3–89; 8:45 am]

BILLING CODE 4160–01–M

Health Care Financing Administration

Public Information Collection Requirements Submitted to the Office of Management and Budget for Clearance

AGENCY: Health Care Financing Administration.

The Department of Health and Human Services (HHS) previously published a list of information collection packages it submitted to the Office of Management and Budget (OMB) for clearance in compliance with the Paperwork Reduction Act (Pub. L. 96–511). The Health Care Financing Administration (HCFA), a component of HHS, now publishes it own notices as the information collection requirements are submitted to OMB. The HCFA has submitted the following requirements to OMB since the last HCFA list was published.

1. *Type of Request:* Reinstatement; *Title of Information Collection:* Claims Processing Assessment System; *Form Number:* HCFA–R–83; *Frequency:* Annually; *Respondents:* State Medicaid Agencies; *Estimated Number of Responses:* 1; *Average Hours per Response:* 1; *Total Estimated Burden Hours:* 1.

2. *Type of Request:* Reinstatement; *Title of Information Collection:* Physician/Supplier Overpayment Reporting System; *Form Number:* HCFA–496; *Frequency:* Upon identification of overpayment; *Respondents:* Business/other for profit and non-profit institutions; *Estimated Number of Responses:* 34,220; *Average Hours per Response:* .025; *Total Estimated Burden Hours:* 856.

3. *Type of Request:* Reinstatement; *Title of Information Collection:* Provider Overpayment Report; *Form Number:* HCFA–481; *Frequency:* Daily; *Respondents:* Businesses/other for profit and non-profit institutions; *Estimated Number of Responses:* 32,500, *Average Hours per Response:* .1; *Total Estimated Burden Hours:* 3,250.

4. *Type of Request:* Revision; *Title of Information Collection:* Home Health Agency Plan of Treatment Forms; *Form Number:* HCFA–485–488; *Frequency:* Occasionally; *Respondents:* Businesses/other for profit, non-profit institutions, and small businesses or organizations; *Estimated Number of Responses:* 3,218,927; *Average Hours per Response:* .75; *Total Estimated Burden Hours:* 2,414,195. This request includes an expanded use of item 13 of Form HCFA–486. The forms will collect information for determining the number of hours per week spent in the home by the nurse or home health aide. The HCFA has requested expedited review by the Office of Management and Budget. In keeping with the requirements for expedited reviews, we are attaching a copy of the form and instructions.

5. *Type of Request:* Extension; *Title of Information Collection:* Supplemental Survey Mechanism; *Form Number:* HCFA–R–7; *Frequency:* Annually; *Respondents:* Individuals/households and State/local governments; *Estimated Number of Responses:* 3,900; *Average Hours per Response:* 1.5; *Total Estimated Burden Hours:* 5,850.

6. *Type of Request:* Revision; *Title of Information Collection:* Fire Safety Survey Report Forms; *Form Number:* HCFA–2786 A–D, F–H, J–M, P–Q; *Frequency:* Annually; *Respondents:* State/local governments; *Estimated Number of Responses:* 20,637; *Average Hours per Response:* 1; *Total Estimated Burden Hours:* 20,637.

Additional Information or Comments: Call the Reports Clearance Officer on 301–966–2088 for copies of the clearance request packages. Written comments and recommendations for the proposed information collections should be sent directly to the following address: OMB Reports Management Branch, Attention: Allison Herron, New Executive Office Building, Room 3208, Washington, DC 20503.

Date: March 28, 1989.

Louis B. Hays,

Acting Administrator, Health Care Financing Administration.

BILLING CODE 4120–03–M